

FEB 3 2005

MAST QUADRANT™ Retractor System
510(k) Summary
February 2005
K043602

I. Company: Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

Contact: Richard W. Treharne, PhD
Senior Vice President Regulatory Affairs

II. Proprietary Trade Name: MAST QUADRANT™ Retractor System

III. Classification Name: Retractors, Manual Surgical Instrument

IV. Regulation Number: Class I Exempt as described in 21 CFR 878.4800 and 888.1100.
Product Code GAD, NBH

V. Product Description

The MAST QUADRANT™ Retractor System is a tubular-based retraction system, designed to provide surgeons with the freedom to retract tissue through any combination of distracting or articulating the blades. The MAST QUADRANT™ System includes instruments used to access the spine by dilating the overlying tissues, as well serving as a retracting device to maintain the access. The system can be used in conjunction with microscopes, light sources, cameras, or other visualization aids.

VII Indications

The MAST QUADRANT™ Retractor System is intended to provide surgeons with instruments such as dilators, retractors, light sources and pedicle access needles used to perform a variety of spinal fixation procedures utilizing a minimally invasive approach.

The MAST QUADRANT™ Retractor System is indicated for visualization of the surgical field in any area of the body cut open during a surgical procedure. When used in the cervical, thoracic, or lumbar spine either from an anterior or posterior direction, for example, the MAST QUADRANT™ Retractors and accessories are intended to aid the surgeon's visualization of the surgical area and allow him/her to perform any type of surgical spinal procedure such as herniated disc repair, visualization of the circumferential decompression of the nerve roots, aiding in the search and removal of nucleus material, spinal fusion, or insertion of spinal implants.

VIII Substantial Equivalence

Documentation was provided which demonstrated the subject MAST QUADRANT™ Retractors to be substantially equivalent to the METRx, MED, Inclusive, and/or INCL Microscopes described in Medtronic Sofamor Danek 510(k) No. K002931 (SE 11/24/00), while the pedicle access needles included in the system are identical to those cleared in the EQUESTRA™ Fluid Delivery System (K040483, SE 07/23/04).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

**Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850**

FEB 23 2005

Richard W. Treharne, Ph.D.
Senior Vice President, Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K043602
Trade/Device Name: MAST QUADRANT™ Retractor System
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical Lamp
Regulatory Class: II
Product Code: FSZ, GAD, NBH
Dated: February 2, 2005
Received: February 4, 2005

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

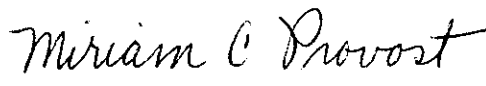
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


for Celia M. Witten, PhD., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: _____ MAST QUADRANT™ Retractor System _____

Indications for Use:

The MAST QUADRANT™ Retractor System is intended to provide surgeons with instruments such as dilators, retractors, light sources and pedicle access needles used to perform a variety of spinal fixation procedures utilizing a minimally invasive approach.

The MAST QUADRANT™ Retractor System is indicated for visualization of the surgical field in any area of the body cut open during a surgical procedure. When used in the cervical, thoracic, or lumbar spine either from an anterior or posterior direction, for example, the MAST QUADRANT™ Retractors and accessories are intended to aid the surgeon's visualization of the surgical area and allow him/her to perform any type of surgical spinal procedure such as herniated disc repair, visualization of the circumferential decompression of the nerve roots, aiding in the search and removal of nucleus material, spinal fusion, or insertion of spinal implants.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)Miriam C. Provost
(Division Sign-Off)**Division of General, Restorative,
and Neurological Devices**510(k) Number K043602

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